

REMARKS

1. **Status Of The Claims.** Claims 1-14 and 27 are pending in the subject application. Claims 1-14 and 27 are rejected under 35 U.S.C.A. Section 103 (a) as being obvious over United States Patent No. 6,604435 to Buchanan (“Buchanan”) and further in view of United States Patent No. 6,230982 to Newton (“Newton”).

Claims 23 and 26 have without prejudice been canceled. Claims 1, 5-12, 14, and 27 have been amended without the addition of any new matter. Claims 2 and 4 are as previously presented. Claims 3 and 13 are as originally presented. Claims 15-22 and 24-25 have been withdrawn. Applicant respectfully reserves the right to pursue any non-elected claims, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

2. **Claim Amendment.** Applicant has amended claim 1 without the introduction of any new matter. Claim 1 has been amended to further include the language “adjustably varying axial location of said injection point of said sperm cells in said fluid stream along said central longitudinal axis to increase resolution of said at least two populations of said sperm cells” into element g. This amendment is supported by the specification. *Publication 20060141628 at Paragraph 0056.* The description makes clear that the step provides:

“selectably variable adjustment of the particle injector (31) allows alteration of fluid stream characteristics in compensation for a change of operation conditions from a first set of operating conditions to a second set of operating conditions whether the change in operation conditions comprises a change in sheath fluid, species of sperm cell, temperature, fluid stream pressure, fluid stream temperature, or otherwise. Importantly, by adjusting the distance between the particle injector (31) and the nozzle orifice (5) increased resolution based on a characteristic of cells can be achieved. With respect to sperm cells, increased resolution of sperm cells separated based upon bearing an X-chromosome or a Y-chromosome can be achieved utilizing the invention, as shown by FIGS. 5-7.”

2. **The Rejections Under 35 U.S.C.A. Section 103(a) As Being Obvious Over Buchanan In View of Newton Are Overcome.** In the present application, the Examiner rejected claims 1-14, and 27 as being unpatentable over Buchanan in view of Newton.

To reject a claim based on combining prior art elements according to known methods, the office must resolve the Graham factual inquiries and provide a finding that the prior art included each element claimed. *MPEP §2143 A (1)*. The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR, 550 US at ___ 82, USPQ2d at 1395*. If any these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. *MPEP §2143 A (1)*. Additionally, “If the proposed modification or combination of the prior art would change the principal of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render claims prima facie obvious” *MPEP Rule §2143.01 VI*. Moreover, “If the proposed modification would render the prior art unsatisfactory for its intended purpose, then there is no motivation to make the proposed modification. *MPEP §2143.01 V*.”

Non-analogous Art. In view of the amendments to claim 1, Applicant believes that Newton is non-analogous art. The Examiner cited Newton to provide an element corresponding to the claimed “adjustably varying location of said injection point of said sperm cells in said fluid stream along said central longitudinal axis to increase resolution of said at least two populations of said sperm cells”. *Claim 14, element g*.

A reference is not reasonably pertinent unless the matter with which it deals logically would have commended itself to an inventor’s attention in considering the claimed invention. *MPEP § 2141.01(a)I*.

Newton would not have commended itself to an inventor's attention because the structure and function of the device taught are not logically pertinent to the structure or function of the claimed method of flow cytometry for reasons as follow:

First, Newton does not teach a device which injects sperm cells or any other particles into a fluid stream. *See Newton, Abstract* (“*A valve for dispersing a fluidic substance into a carrier fluid*”). The Newton device does not inject any particles at an injection point along the central longitudinal axis of a fluid stream as claimed. This is because the function of the Newton device is to “disperse as tiny droplets or micelle like moieties prior to integrating with the flow stream” *Newton, col. 5, lines 15-17*. The Newton device provides a structure “in order to thoroughly mix and precisely meter small amounts of fluidic substances into the flowing stream”. The function of the Newton valve to thoroughly mix tiny droplets of liquid into fluid stream is not logically pertinent to injecting particles into a fluid stream for flow cytometry.

Second, Newton does not teach a device for adjustably varying location of the injection point of any particles in the fluid stream along the central longitudinal axis to increase resolution of populations of particles. Rather, Buckley teaches that “the valve 100 is inserted into the irrigation pipe 152 so that the dispersed fluidic substances 158 enters the flowing stream 156 at its point of highest velocity. The flowing stream 156 with the fluidic substance dispersed therein is distributed over the irrigated land through a pop up valve 154.” *Newton, col. 9, lines 37-42*. Newton states that “the valve is mounted by a bulkhead 42, into a pipe 46 carrying a flowing stream 44 so that. . .fluidic substances 48 being dispersed is injected into the flowing stream 44 substantially near the center of the diameter of the pipe.” *Buckley, col. 4, ll. 48-52*. The function of the Newton valve is to place the valve as near the center of the diameter of the pipe to mix fluids and not to vary location of the injection point of particles along the central axis of the fluid stream to better separate particles from one another.

Third, even if Newton dispersed particles and not fluids, thoroughly mixing the particles in the fluid stream would act to decrease resolution of particles and not increase resolution of particles as claimed.

Because Newton teaches a structure which functions entirely different than that of the claimed invention (as further discussed below), Applicant believes that Newton is non-analogous art and respectfully requests that the reference be withdrawn.

Combination of Buchanan and Newton Does Not Teach All Elements of the Claimed Invention. The combination of Buchanan and Newton does not teach all the limitations of the invention of claim 1.

The Examiner indicates that Buchanan does not specifically teach the adjustable injection point of claim 1, element g. *Office Action at Page 3.* Applicant believes that Buchanan does not even suggest “adjustably varying location of the injection point”. Buchanan teaches as to a fixed configuration of nozzle a fixed non-adjustable location or injection point.

Because Buchanan does not teach the limitation of an adjustably varying location of the injection point, the Examiner has combined Buchanan with Newton. The Examiner indicates that Newton teaches of an adjustable valve for varying the position of injection into a flowing stream (Claim 29). *Office Action at Page 3.* However, Newton, claim 29, does not provide so broad a recitation. Claim 29 of Newton recites “slidably adjusting the position of the valve with respect to the center of the stream”. This recitation is limited to the teaching of radial adjustment (“substantially near the center of the diameter of the pipe 46. This locates the dispersed fluidic substance in that portion of the flowing stream 44 with the highest flow velocity.”) and does not teach or suggest adjustably varying axial adjustment along the central longitudinal axis as claimed for any purpose. Accordingly, the combination of Buchanan and Newton does not teach the limitation of claim 1, element g. of adjustably varying axial adjustment along the central longitudinal axis as claimed.

Because the combination does not does not teach all the limitations of claim 1 as required by *MPEP §2143 A (1)*, Applicant respectfully requests reconsideration of claim 1 and withdrawal of the obviousness rejection based on the combination of Buchanan and Newton

Now referring to claim 5, the Examiner indicates that it “is inherent to inject sperm cells of the first and second species at different injection points.” Inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on that which is unknown. *In re Sporman*, 363 F.2d 444 (CCPA 1966); *MPEP §2112 IV*. The combination of Buchanan and Newton do not teach injecting sperm cells of a first species of mammal and the sperm cells of a second species of mammal at different injection points. The fact that a certain thing may occur or be present in the art is not sufficient to establish inherency. *MPEP §2112 IV*.

Accordingly, Applicant respectfully requests reconsideration of claim 5 and withdrawal of the obviousness rejection based on the combination of Buchanan and Newton due to any inherency.

Now referring to claim 6, the Examiner indicates that adjusting position of a particle injector is equivalent to the slidable valve of Newton. Applicant disagrees, as pointed out in the above remarks, Newton does not inject particles and is not a particle injector.

Now referring to claims 11 and 12, as to each the Examiner indicates that Buchanan teaches adjusting injection point by use of a beveled tip. Applicant respectfully disagrees. Beveling the tip does not adjust the injection point of the particles. Applicant has amended claims 11 and 12 to make clear that adjustably varying location of the injection point is “in response to” fluid stream characteristics and altered fluid stream characteristics. The combination of Buchanan and Newton does not teach adjustably varying location of the injection point in response to any fluid conditions or altered fluid conditions.

Because the combination does not does not teach all the limitations of claim 6, 11 or 12 as required by *MPEP §2143 A (1)*, Applicant respectfully requests reconsideration of claims 6, 11, and 12 and withdrawal of the obviousness rejection based on the combination of Buchanan and Newton.

Lack of Motivation to Combine References. Applicant believes that there is a lack of motivation to combine Buchanan with Newton. If the proposed modification or combination of the prior art would change the principal of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render claims prima facie obvious” *MPEP Rule §2143.01 VI*. As explained in the remarks above, the Newton reference teaches radially inserting a valve into the fluid stream of a pipe to disperse droplets of liquid. Buchanan teaches aligning the sample tube (3) within the nozzle of a flow cytometer generally in line with the central longitudinal axis of the nozzle to entrain particles in the fluid stream with minimal disruption of the fluid stream. *Buchanan, Figure 1*. It is well understood that by those of skill in the art of flow cytometry that the sample fluid containing particles should be surrounded by an undisrupted flow of sheath fluid. Modifying Buchanan to include the valve of Newton would change this principal of operation in two ways. First, by placing a radial member in the fluid stream as shown and taught by Newton (see Newton, Figure 3), the laminar flow within the nozzle would be disrupted. Second, dispersing fluid into the fluid stream as taught by Newton (Newton, col. 5, lines 14-17) to mix a sample fluid with the fluid stream would further disrupt the laminar flow of the fluid stream within the nozzle. This would substantially change the principle of operation of the Buchanan flow cytometer.

Also, “If the proposed modification would render the prior art unsatisfactory for its intended purpose, then there is no motivation to make the proposed modification. *MPEP §2143.01 V*. By introducing the radial member as taught by Newton and dispersing liquid as taught by Newton as explained in above remarks would render the Buchanan unsatisfactory for its intended purpose of entraining particles in a sample stream which is subsequently broken into droplets each containing one particle. By introducing a radial member and dispersing liquid into the nozzle of a flow cytometer as taught by Newton. the laminar flow in the nozzle would not be generated and the particles would be mixed into the sheath fluid within the nozzle. The particles would not be entrained one each within the droplets as required for subsequent analysis and sorting.

Because the proposed modification would change the principal of operation or render the Buchanan reference unsatisfactory for its intended purpose, a case of obvious cannot be

established by the combination of Buchanan and Newton. Accordingly, Applicant respectfully requests reconsideration claims 1-14 and 27 and withdrawal of the Section 103(a) rejection based on the combination of Buchanan and Newton.

3. **Request For Telephonic Interview.** Applicant respectfully requests a telephonic interview with the Examiner to address any remaining concerns that the Examiner may have with respect to the Section 102 concerns.

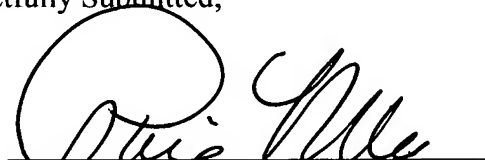
CONCLUSION

Claims 23 and 26 have without prejudice been canceled. Claim 1, 5-12, 14, and 27 have been amended without the addition of any new matter. Claims 2 and 4 are as previously presented. Claims 3 and 13 are as originally presented. Claims 15-22 and 24-25 have been withdrawn. Applicant believes that the amendments to the claims along with the remarks overcome the Section 103 rejections based on the combination of Buchanan and Newton. Applicant believes that claims 1-14 and 27 are now in condition for allowance and respectfully requests allowance of claims 1-14 and 27.

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Respectfully Submitted,

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